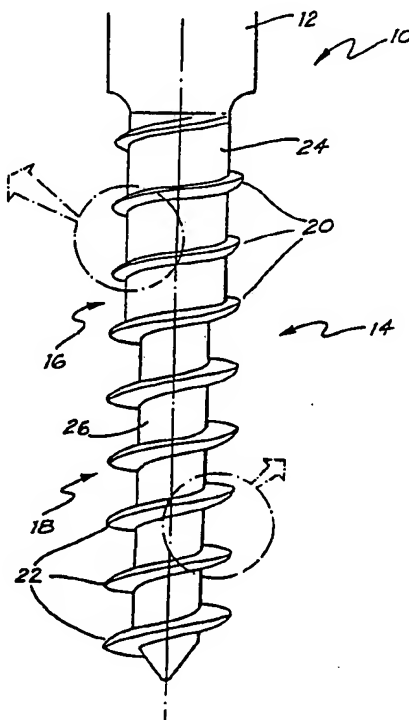


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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁴ : A61B 17/58</p>	<p>A1</p>	<p>(11) International Publication Number: WO 90/02526 (43) International Publication Date: 22 March 1990 (22.03.90)</p>
<p>(21) International Application Number: PCT/AU89/00386 (22) International Filing Date: 11 September 1989 (11.09.89) (30) Priority data: PJ 0351 9 September 1988 (09.09.88) AU (71) Applicant (for all designated States except US): AUSTRALIAN DEFENCE INDUSTRIES PTY. LIMITED [AU/AU]; 10-12 Brisbane Avenue, Barton, ACT 2600 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): BLAIR, David, Keith, Livingston [AU/AU]; 87A Hawkesbury, Springwood, NSW 2777 (AU). SELMES, John, Raymond [AU/AU]; 46 Explorers Road, Katoomba, NSW 2780 (AU). (74) Agent: F.B. RICE & CO.; 28A Montague Street, Balmain, NSW 2041 (AU).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.</p> <p>Published With international search report.</p>
<p>(54) Title: SCREW</p> <p>(57) Abstract</p> <p>The present invention discloses a screw (10) adapted for insertion into a bone and in particular a vertebra. The screw (10) is divided into two distinct regions (16 and 18) with the depth of the screw thread (20, 22) in each region being different to that in each other region whilst the overall diameter of the screw (10) is substantially constant over the length of the screw (10).</p> 		

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SCREW

Field of the Invention

The present invention relates to a screw having a multi-thread profile adapted for insertion into bone, and in particular, into a vertebra.

5 Following fracture of a bone it is necessary to immobilise the fractured bone, or limb, to allow the bone fragments to heal. In some cases, in particular in fractures of the spine, this is achieved using a fixation system comprising screws and a supporting plate or rod.

10 In the case of a spinal fracture this fixation system is used to immobilise one or more spinal segments till a bone graft placed around the segment to be immobilised gains sufficient strength to immobilise the segment.

15 The fixation system requires anchorage points above and below the segment to be fused to which are attached longitudinal bars or plates providing the longitudinal stability. In the case of a spinal fracture the screws are typically referred to as pedicle screws as they are passed through the pedicle of the vertebra. Each pedicle
20 screw is set in a hole drilled down through the pedicle into the centrum or body of the vertebra. The pedicle is the solid narrow bone adjoining the centrum which supports the neural arch. The centrum is composed of a type of bone called cancellous. Cancellous bone is crumbly,
25 peppered with small voids, and not very strong.

 In the case of a spinal fracture, the pedicle screw is expected to maintain a high degree of anchorage in the supporting vertebra irrespective of the applied stress conditions. It must be resilient and strong enough to
30 withstand the effects of both static and dynamic loading on the spine and not fracture or fail. The body of the screw, especially the upper portion needs, therefore, to be as broad as possible to maximise strength. However, as the major thread diameter of the screw must be
35 significantly less than the diameter of the pedicle at its

narrowest point, a shallow thread profile is obligatory.

As a consequence of the somewhat mutually exclusive requirements of maximum screw strength and preservation of pedicle integrity, prior art pedicle screws typically have
5 a uniformly wide body with a low thread profile to minimise the major diameter of the screw. As a result of using uniformly low thread profile, existing pedicle screws are liable to fail through extraction, as they may be pulled out of the crumbly cancellous bone when
10 subjected to stress applied under extreme loading. They are, therefore, suspect means of support and/or stability for use in a spinal fracture fixation system.

As strength and stability are major operational factors, the present inventors have designed a novel screw
15 of relatively uniform major thread diameter with distinct segments of different thread profiles.

Accordingly, the present invention consists in a screw adapted for insertion into a bone, the screw being characterised in that the screw is divided into at least
20 two distinct regions, the depth of the screw thread in each region being different to that in each other region, whilst the overall diameter of the screw is substantially constant over the length of the screw.

In a preferred embodiment of the present invention
25 the screw is divided into two distinct regions.

In a further preferred embodiment of the present invention the depth of the screw thread in the region proximate the head of the screw is less than the depth of the screw thread in the region remote from the screw head.

30 In yet a further preferred embodiment of the present invention the screw is adapted for insertion into a vertebra through its pedicle.

It is presently preferred that the upper face of the screw is substantially perpendicular to the base of the
35 screw. As will be recognised by persons skilled in the

art such an arrangement results in the screw having greater resistance to extraction.

In order that the nature of the present invention may be more clearly understood a preferred form thereof will now be described with reference to the accompanying drawings, in which:-

Figure 1 shows a longitudinal cross-section of the screw of the present invention;

Figure 2 shows an expanded cross-sectional view of the screw thread of the upper region of the screw shown in Fig. 1; and

Figure 3 shows an expanded cross-sectional view of the screw thread of the lower region of the screw shown in Fig. 1.

As shown in Figure 1 the screw 10 comprises a head 12 (detail not shown) and a body portion 14. The body portion is divided into two distinct regions 16 and 18, with region 16 being proximate screw head 12. As can clearly be seen in this drawing the depth of the screw thread 20 in region 16 is less than the depth of the screw thread 22 in region 18, whilst the diameter of the base 24 in region 16 is greater than the diameter of the base 26 in region 18. This results in the overall diameter of the screw is substantially constant over the entire length of the screw.

As is best shown in Figs. 2 and 3 the upper face of screw threads 20 and 22 are perpendicular to bases 24 and 26 respectively.

As will be readily apparent to persons skilled in the art, when the screw of the present invention is adapted for insertion into a vertebra the segment of the screw contacting the pedicle retains maximum strength by employing a low thread profile on a high diameter base, whilst the segment of the screw contacting the centrum maximises stability by the use of a thread profile which

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is as deep as possible to obtain optimum anchorage in this type of bone on a low (narrow) diameter base.

This screw therefore provides firmer anchorage in the vertebral body without sacrificing strength through the use
5 of a wide base - low thread profile in its upper region which will be in the pedicle, and a narrow base - high thread profile in the lower half of the shaft which will be in the cancellous bone of the centrum.

From the foregoing description, it should be apparent
10 that the invention encompasses an advantageous advance in the art. Further, it should be clear that the invention may be embodiment in other specific forms without departing from the spirit of the essential characteristics thereof. The present embodiments are, therefore, to be
15 considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A screw adapted for insertion into a bone, the screw being characterised in that the screw is divided into at least two distinct regions, the depth of the screw thread in each region being different to that in each other region, whilst the overall diameter of the screw is substantially constant over the length of the screw.
2. A screw as claimed in claim 1 in which the screw is divided into two distinct regions.
3. A screw as claimed in claim 1 or claim 2 in which the depth of the screw thread in the region proximate the screw head is less than the depth of the screw thread in the region remote from the screw head.
4. A screw as claimed in any one of claims 1 to 3 in which the screw is adapted for insertion into a vertebra through its pedicle.
5. A screw substantially as hereinbefore described with reference to the accompanying drawing.

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FIG. 2

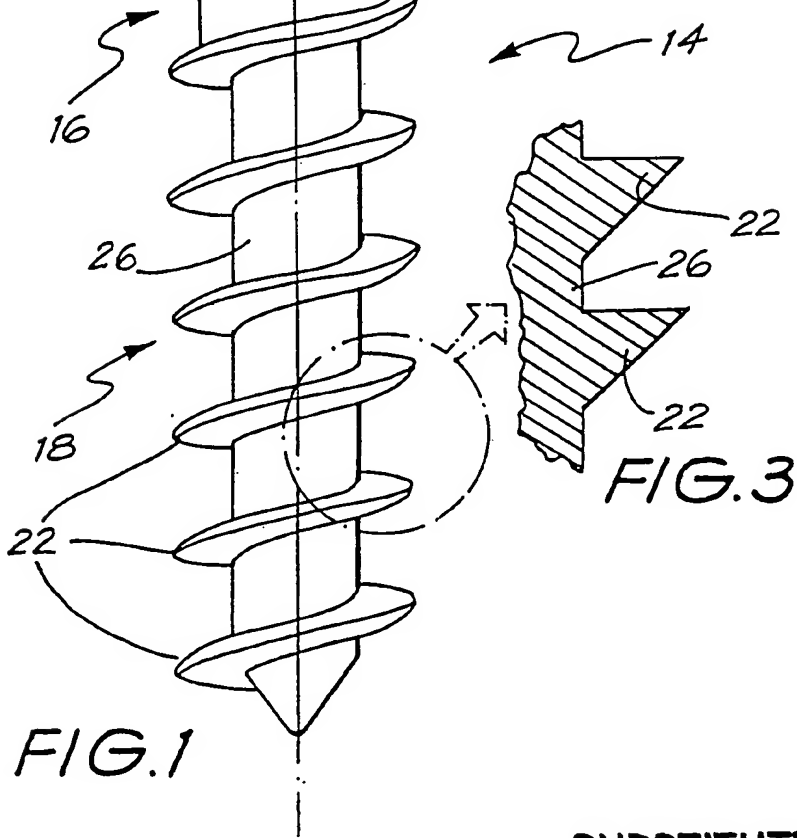
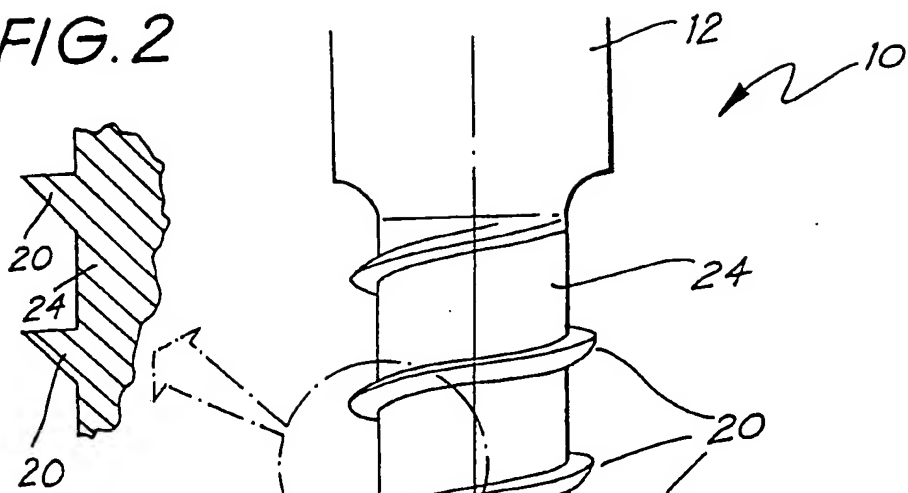


FIG. 3

FIG. 1

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No. PCT/AU 89/00386

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 6		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ⁴ A61B 17/58		
II. FIELDS SEARCHED		
Minimum Documentation Searched 7		
Classification System	Classification Symbols	
IPC ⁴	A61B 17/58, F16B 35/04, 35/00	
IPC ³	A61B 17/18	
Documentation Searched other than Minimum Documentation to the extent that such documents are included in the fields searched 8		
III. DOCUMENTS CONSIDERED TO BE RELEVANT 9		
Category*	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages 12	Relevant to Claim No 13
X	AU-B- 33298/78 (51681) (INTERFIX LIMITED)	1-3
Y	23 August 1979 (23.08.79)	4
Y	AU-B- 13441/76 (503575) (DOWNS SURGICAL LIMITED)	4
Y	3 November 1977 (03.11.77)	1-3
Y	EP-A- 144503 (FRIEDR BOESNER GmbH) 19 June 1985 (19.06.85)	1-3
Y	AU-B- 59658/69 (452974) (ILLINOIS TOOL WORKS INC) 25 February 1971 (25.02.71)	1-3
(continued....)		
<p>* Special categories of cited documents: 10</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
16 November 1989 (16.11.89)	28 November 1989	
International Searching Authority	Signature of Authorized Officer	
Australian Patent Office	A. DUKE a.w. Duke	

Form PCT/ISA/210 (second sheet) (January 1985)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

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Y	FR-A- 1562811 (EDELMA A.E. and LINKOW L.I.) 11 April 1969 (11.04.69)	1-3
Y	EP-A- 129404 (ITW LIMITED) 27 December 1984 (27.12.84)	1-3
A, P	AU-A- 12800/88 (SOCIETE DE FABRICATION DE MATERIEL ORTHOPEDIQUE) 15 September 1988 (15.09.88)	1-4

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 1

This international search report has not been established in respect of certain claims under Article 17(2)(e) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers , because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4 (8):

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 2

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 89/00386

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members			
AU 13441/76	CA 1064353 GB 1551706	DE 2618344 JP 51131192	FR 2309200 US 4041939		
AU 12800/88	EP 283373	FR 2612071	JP 1076847		
EP 144503	EP 196658	ES 534898	ES 8504353		
EP 129404	NO 842391	CA 974438	CA 975510		
CH 546351	DE 2257112 IT 974837 US 3901066	FR 2162978 US 3789644 US 3787758	GB 1385398 US 3850215		

END OF ANNEX